REMARKS

In response to the Office Action mailed July 1, 2008, please consider the following remarks:

1. Status of Claims

In applicants' Preliminary Amendment filed November 17, 2003, claims 1-26 were canceled without prejudice, claim 27 was amended, claim 28 was retained as originally filed, and claims 29-39 were introduced. Claims 27-39 were canceled and claims 40-41 were added in the Amendment filed January 17, 2007. Claims 40-41 were amended May 16, 2008. Thus, claims 40-41 are currently under examination and are not further amended herein. New claim 42 has been added corresponding to claim 41 (and original claim 28). Without acquiescing to the Examiner's indefiniteness rejection, claim 42 has been added merely to further clarify the subject matter of the claim and the distinction between antigen and antibody employed in the combination assay by specifying in all aspects of clause a) and b) that the "HIV-1 antigen" is an "HIV-1 p24 core antigen", by specifying in all aspects of clause d) and e) that the "HIV-2 antigen" is an "HIV-2 p22 core antigen", and by specifying in all aspects of clauses g), h) and i) that the antigens bound by the antibodies of the invention are "one or more antigens selected from the group consisting of HIV-1 antigen and HIV-2 antigen." No new matter has been added as a result of these amendments.

2. Definiteness of the Pending Claims

Claims 40 and 41 were rejected in the Office Action as being indefinite for purportedly failing to set for the all the salient characteristics required to perform the assay in any meaningful manner. The Office Action states that the assay methodology as claimed "does not allow the skilled artisan to ascertain the difference between a positive antibody response in the sample, a positive antigen response in the sample, or both a positive antibody and antigen response in the sample." On this basis, the Office Action asserts that the "scientific objective and the assay steps of the claim remain vague and indefinite."

Applicants respectfully disagree.

The application sets forth, among other things, monoclonal antibodies to human immunodeficiency virus (HIV). As described in the first paragraph of the Summary:

> Such antibodies also may be used in assays which detect HIV antigen and in combination assays that simultaneously detect HIV antigen and HIV antibody. In a preferred embodiment of the present invention, only two complementary, high affinity, broadly specific mouse monoclonal antibodies are required to detect equivalent amounts of core proteins from HIV-1 Group M, HIV-1 Group O, and HIV-2.

As described in the application in the paragraph bridging pages 13-14 (Summary):

> The present invention also includes methods of simultaneously detecting both antigen and antibody to HIV-1 and/or HIV-2 in a patient sample. One such method involves detecting 1) one or more antibodies selected from the group consisting of HIV-1 antibody and HIV-2 antibody, and 2) one or more antigens selected from the group consisting of HIV-1 antigen and HIV-2 antigen, in a test sample suspected of containing one or more of the antibodies and one or more of said antigens, comprising the steps of: a) contacting the test sample with at least one HIV-1 antigen which binds to HIV-1 antibody for a time and under conditions sufficient for the formation of HIV-1 antigen/HIV-1 antibody complexes; b) detecting the HIV-1 antigen/HIV-1 antibody complexes, presence of the complexes indicating presence of HIV-1 antibody in the test sample; c) contacting the test sample with at least one HIV-2 antigen which binds to HIV-2 antibody for a time and under conditions sufficient for the formation of HIV-2 antigen/HIV-2 antibody complexes; d) detecting the HIV-2 antigen/HIV-2 antibody complexes, presence of the complexes indicating presence of HIV-2 antibody in the test sample; e) contacting the test sample with at least one monoclonal antibody which specifically binds to Human Immunodeficiency Virus-1 protein p24 and Human Immunodeficiency Virus-2 protein p26 for a time and under conditions sufficient for the formation of antibody/antigen complexes; and f) detecting the complexes, presence of the complexes indicating presence of at least one antigen selected from the group consisting of HIV-1 antigen and HIV-2 antigen, in the test sample. Again, it is preferable to utilize certain pairs of monoclonal antibodies in connection with HIV-1 and HIV-2 antigen detection (e.g., 120A-270 and 115B-151).

This method is further detailed on pages 14-16, as well as on page 19, which details that antibody employed as conjugate (e.g., in step h) of claim 41) binds to an

epitope distinct from and compatible with the binding of the capture antibody being detected. Page 19-20 further documents that the conjugate can be either labeled antigen or anti-antibody capable of binding the antibody.

As further described on page 23:

> Also, it should be noted that the monoclonal antibodies of the present invention may be utilized in a combination assay which detects: 1) antigens, such as those described above (e.g., p24 and p26) and 2) antibodies to HIV (by use of, for example, envelope antigens (e.g., HIV-1 group M and O gp41 and HIV-2 gp36). Any such combination assay, which utilizes the monoclonal antibodies of the present invention, is considered to be within the scope of the invention.

Accordingly, the subject invention clearly contemplates combination assays for the simultaneous detection of both antigen and antibody in a sample, and without need, for example, for ascertaining a difference between a positive antibody response in the sample, a positive antigen response in the sample, or both a positive antibody and antigen response in the sample. On this basis, applicants assert that that scientific objective and the assay steps of the claim are concrete and definite.

For the foregoing reasons, applicants submit that the indefiniteness rejection is unwarranted with respect to claims 40 and 41 and request that it be withdrawn and not applied to newly added claim 42.

CONCLUSION

The application is considered in good and proper form for allowance. Applicants believe they have addressed all the rejections in the Office communication. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject patent application, the Examiner is invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,
Lou, et al.

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